AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions and listings of claims in this application:

1. (Currently Amended) A gel formulation for the transdermal or transmucosal administration of an active agent comprising:

at least one active agent of a hormone, provided when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount and further provided that, when the active agent is testosterone, the testosterone is ~~not used as the only active ingredient or if used as~~ the sole active agent and it, ~~the testosterone~~ is present in an amount of 1% or less by weight of the formulation;

a gelling agent; and

a delivery vehicle comprising an alkanol, a polyalcohol and a permeation enhancer of a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces;

wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during use of the formulation, and

wherein the alkanol is present in an amount between about 5 to 80% by weight of the delivery vehicle, the polyalcohol is present in an amount between about 1% to 15% by weight of the delivery vehicle, and the permeation enhancer is present in an amount between about 0.2% to 15% by weight of the delivery vehicle so that the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

Claim 2. (Cancelled)

3. (Previously Presented) The formulation of claim 1, wherein the active agent is estradiol present in an amount between about 0.01% to 2% of the formulation; the alkanol is present in an amount between about 20 to 65% of the formulation; the polyalcohol is propylene

glycol; the permeation enhancer is diethylene glycol monoethyl ether; the gelling agent is present in an amount of between 0.05% to about 4% of the formulation, and the formulation further comprises a neutralizing agent present in an amount between about 0.05% and 1% of the formulation, and water present in an amount between about 20% to 65% of the formulation.

4. (Original) The formulation of claim 3, further comprising a sequestering agent.

5. (Previously Presented) The formulation of claim 1, wherein the alkanol is in combination with water to form a hydroalcoholic mixture, the hydroalcoholic mixture is present in an amount of between about 40 to about 98% by weight of the delivery vehicle, and the alkanol is present in an amount of between about 5% to 80% by weight of the mixture, and the water is present in an amount of between about 20% to 95% by weight of the mixture.

6. (Previously Presented) The formulation of claim 1, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 2:1 to 1:1 and the total amount of polyalcohol and permeation enhancer is not more than 15% of the formulation.

7. (Currently Amended) The formulation of claim 1, wherein the alkanol is a C_2 to C_4 alcohol selected from the group consisting of ethanol, isopropanol, and n-propanol, the polyalcohol is propylene glycol or polypropylene glycol, and the permeation enhancer is a monoalkyl ether of diethylene glycol ~~ether~~.

8. (Currently Amended) The formulation of claim 1, wherein the active agent is androgen, estrogen, progestin, or a combination thereof other than the combination of estrogen and progestin.

9. (Original) The formulation of claim 8, wherein the androgen is selected from the group consisting of: testosterone, 17-β-hydroxyandrostenone, testosterone esters, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate,

androstenediol-3-acetate-17-benzoate, androstenedione, sodium dehydroepiandrosterone sulfate, 4-dihydrotestosterone, 5 adihydrotestosterone, dromostanolone, dromostanolone propionate, ethylestrenol, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexanepropionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, and stanozolol or any combination thereof.

10. (Currently Amended) The formulation of claim 8, wherein the estrogen is selected from the group consisting of: 17 beta-estradiol, estradiol, estradiol benzoate, estradiol 17 beta-cypionate, estriol, estrone, ethynil estradiol, mestranol, moxestrol, mytatrienediol, polyestradiol phosphate, quinestradiol, and quinestrol or any combination thereof.

11. (Previously Presented) The formulation of claim 1, wherein the formulation further comprises at least one of a neutralizing agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, or emollient.

Claim 12. (Cancelled)

13. (Currently Amended) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the gel formulation of claim 1 ~~wherein the active agent is a hormone which is effective~~ for treating at least one symptom of the hormonal disorder selected from the group consisting of hypogonadism, female menopausal symptoms, female sexual dysfunction, hypoactive sexual desire disorder, and adrenal insufficiency, and wherein the administration of the formulation decreases the frequency of at least one clinical symptom of the hormonal disorder.

Claim 14. (Cancelled)

15. (Currently Amended) The method of claim 13, wherein the active agent is an androgen, estrogen, progestin, or a combination thereof other than the combination of estrogen and progestin.

16. (Original) The method of claim 13, wherein the androgen is selected from the group consisting of : testosterone, 17-β-hydroxyandrostenone, testosterone esters, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androstenediol, androstenediol-3-acetate, androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, sodium dehydroepiandrosterone sulfate, 4-dihydrotestosterone, 5 adihydrotestosterone, dromostanolone, dromostanolone propionate, ethylestrenol, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexanepropionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, and stanozolol or any combination thereof.

17. (Original) The method of claim 16, wherein the subject is a female subject, the active agent is testosterone and the therapeutically effective dosage of testosterone is from about 2.2 milligrams to about 0.88 grams each 24 hours.

18. (Original) The method of claim 16, wherein the subject is a female subject, the active agent is testosterone, and further wherein the method increases serum levels of the testosterone to about 142 nanograms per deciliter.

19. (Original) The method of claim 16, wherein the subject is a female subject, the active agent is testosterone, and further wherein the method increases serum levels of the testosterone to about 17 picograms per milliliter.

20. (Original) The method of claim 15, wherein the estrogen is selected from the group consisting of: 17 beta-estradiol, estradiol, estradiol benzoate, estradiol 17 beta-cypionate, estriol, estrone, ethynil estradiol, mestranol, moxestrol, mytatrienediol, polyestradiol phosphate, quinestradiol, and quinestrol or any combination thereof.

21. (Original) The method of claim 15, wherein the progestin is selected from the group consisting of: allylestrenol, anagestone, chlormadinone acetate, delmadinone acetate, demegestone, desogestrel, dimethisterone, dydrogesterone, ethynilestrenol, ethisterone,

ethynodiol, ethynodiol diacetate, flurogestone acetate, gestodene, gestonorone caproate, haloprogesterone, 17-hydroxy-16-methylene-progesterone, 17 alpha -hydroxyprogesterone, 17 alpha-hydroxygesterone caproate, lynestrenol, medrogestone, medroxyprogesterone, megestrol acetate, melengestrol, norethindrone, norethindrone acetate, norethynodrel, norgesterone, norgestimate, norgestrel, norgestrienone, 19-norprogesterone, norvinisterone, pentagestrone, progesterone, natural progesterone, promegestone, quingestrone, and trengestone or any combination thereof.

22. (Original) The method of claim 20, wherein the subject is a female subject, the active agent is estradiol and the therapeutically effective dosage of estradiol is from about 0.375 to about 1.5 milligrams each 24 hours.

23. (Original) The method of claim 20, wherein the subject is a female subject, the active agent is estradiol and the free serum concentration of estradiol is increased to about 8.8 nanograms per deciliter.

24. (Original) The method of claim 20, wherein the subject is a female subject, the active agent is estradiol, and further wherein the method increases serum levels of estrone to about 10.4 nanograms per deciliter.

25. (Original) The method of claim 20, wherein the subject is a female subject, the active agent is estradiol, and further wherein the method increases serum levels of estrone to about 193 nanograms per deciliter.

26. (Currently Amended) The method of claim 13, wherein the active agent is a combination of two different active agents administered concurrently other than the combination of estrogen and progestin.

27. (Previously Presented) The method of claim 13, wherein a female subject is treated for hypogonadism, female menopausal symptoms, or female sexual disorder, and the formulation comprises testosterone in combination with a further active agent selected from the

group consisting of estrone, estradiol, 17 β estradiol, ethynil estradiol, estriol succinate, estriol dihexanate and estriol sulfamate.

Claim 28. (Cancelled)

29. (Original) The method of claim 13, wherein a male subject is treated for hypogonadism, and the active agent includes at least one androgen.

30. (Previously Presented) The method of claim 13, wherein the at least one androgen includes methyltestosterone in combination with methandrostenolone.

31. (Original) The method of claim 13, wherein the method includes treating a subject for adrenal insufficiency, and the active agent includes dehydroepiandrosterone (DHEA).

Claims 32 to 36. (Cancelled)

37. (Currently Amended) A formulation for the transdermal or transmucosal administration of an active agent consisting essentially of:

at least one active agent of a hormone, provided when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount and further provided that, when the active agent is testosterone, the testosterone is ~~not used as the only active ingredient or if used as~~ the sole active agent and it ~~, the testosterone~~ is present in an amount of 1% or less by weight of the formulation;

a gelling agent; and

a delivery vehicle comprising an alkanol, a polyalcohol and a permeation enhancer of a monoalkyl ether of diethylene glycol in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces;

wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids, and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during use of the formulation; and

wherein the alkanol is present in an amount between about 5 to 80% by weight of the delivery vehicle, the polyalcohol is present in an amount between about 1% to 15% by weight of the delivery vehicle, and the permeation enhancer is present in an amount between about 0.2% to 15% by weight of the delivery vehicle so that the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

Claims 38 and 39. (Cancelled)

40. (Previously Presented) The formulation of claim 37, wherein the alkanol is in combination with water to form a hydroalcoholic mixture, the hydroalcoholic mixture is present in an amount of between about 40 to about 98% by weight of the delivery vehicle, and the alkanol is present in an amount of between about 5% to 80% by weight of the mixture, and the water is present in an amount of between about 20% to 95% by weight of the mixture .

41. (Previously Presented) The formulation of claim 37, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 2:1 to 1:1 and the total amount of polyalcohol and permeation enhancer is not more than 15% of the formulation.

42. (Previously Presented) The formulation of claim 37, wherein the alkanol is a C_2 to C_4 alcohol selected from the group consisting of ethanol, isopropanol, and n-propanol, and the polyalcohol is propylene glycol or polypropylene glycol.

43. (Currently Amended) The formulation of claim 37, wherein the active agent is androgen, estrogen, or progestin, or a combination thereof other than the combination of estrogen and progestin.

44. (Original) The formulation of claim 43, wherein the androgen is selected from the group consisting of: testosterone, 17-β-hydroxyandrostenone, testosterone esters, methyl testosterone, testolactone, oxymetholone, fluoxymesterone, androsterone, androsterone acetate, androsterone propionate, androsterone benzoate, androstenediol, androstenediol-3-acetate,

androstenediol-17-acetate, androstenediol-3,17-diacetate, androstenediol-17-benzoate, androstenediol-3-acetate-17-benzoate, androstenedione, sodium dehydroepiandrosterone sulfate, 4-dihydrotestosterone, 5 adihydrotestosterone, dromostanolone, dromostanolone propionate, ethylestrenol, nandrolone phenpropionate, nandrolone decanoate, nandrolone furylpropionate, nandrolone cyclohexanepropionate, nandrolone benzoate, nandrolone cyclohexanecarboxylate, oxandrolone, and stanozolol or any combination thereof.

45. (Original) The formulation of claim 43, wherein the estrogen is selected from the group consisting of: 17 beta-estradiol, estradiol, estradiol benzoate, estradiol 17 beta-cypionate, estriol, estrone, ethynil estradiol, mestranol, moxestrol, mytatrienediol, polyestradiol phosphate, quinestradiol, and quinestrol or any combination thereof.

46. (Previously Presented) The formulation of claim 37, wherein the formulation further comprises at least one of a neutralizing agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, or emollient.

47. (Original) The formulation of claim 37, wherein the formulation is in the form of a gel, lotion, cream, spray, aerosol, ointment, emulsion, suspension, liposomal system, lacquer, patch, bandage, or occlusive dressing.

Claims 48 to 55. (Cancelled)

56. (Currently Amended) A kit for treating a subject for increasing serum levels of a hormone ~~an active agent~~ in a subject comprising:

a gel formulation according to claim 1; and

a container that retains the formulation and includes a dispenser for releasing or applying a predetermined dosage or volume of the formulation upon demand.

57. (Original) The kit of claim 56, wherein the dispenser automatically releases the predetermined dosage or volume upon activation by a user.

58. (Original) The kit of claim 56, wherein the dispenser is a pump.

59. (Currently Amended) The ~~gel~~ formulation of claim 37, wherein the at least one active agent comprises dehydroepiandrosterone (DHEA).

60. (Currently Amended) A gel formulation for the transdermal or transmucosal administration of an active agent for treating a hormonal disorder in a subject comprising:

at least one active agent of a hormone which is effective for treating at least one symptom of the hormonal disorder and in an amount effective for that purpose, provided that when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount;

a gelling agent; and

a delivery vehicle comprising an alkanol, ~~poly~~propylene glycol, and a permeation enhancer of a monoalkyl ether of diethylene glycol ~~ether~~ in an amount sufficient to provide permeation enhancement of the active agent through mammalian dermal or mucosal surfaces, wherein the alkanol is present in an amount between about 20 to 65% by weight of the delivery vehicle, the ~~poly~~propylene glycol is present in an amount between about 1% to 15% by weight of the delivery vehicle, and the permeation enhancer is present in an amount between about 0.2% to 15% by weight of the delivery vehicle, with the polyalcohol and permeation enhancer being present in a weight ratio of 2:1 to 1:1, and with the alkanol being ethanol, isopropanol, or n-propanol, so that the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces; and

wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids and long-chain fatty esters to avoid undesirable odor and irritation from such compounds during use of the formulation and the delivery vehicle facilitates absorption of the at least one active agent by the dermal or mucosal surfaces so that transfer or removal of the formulation from such surfaces is minimized.

61. (Previously Presented) A kit for treating a subject for increasing serum levels of an active agent in a subject comprising:

a gel formulation according to claim 60; and

a container that retains the formulation and includes a dispenser for releasing or applying a predetermined dosage or volume of the formulation upon demand.

62. (Previously Presented) The kit of claim 61, wherein the dispenser automatically releases the predetermined dosage or volume upon activation by a user.

63. (Previously Presented) The kit of claim 61, wherein the dispenser is a pump.

64. (Previously Presented) The formulation of claim 1, wherein the active agent is testosterone present in an amount of 1% or less by weight of the formulation.

65. (Previously Presented) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the gel formulation of claim 64.

66. (Previously Presented) The formulation of claim 37, wherein the active agent is testosterone present in an amount of 1% or less by weight of the formulation.

67. (Previously Presented) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the gel formulation of claim 66.

68. (Previously Presented) A method for treating hormonal disorders in a subject, the method comprising administering to a subject in need of such treatment the gel formulation of claim 60.